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09/261,329

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HM22/0521

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EXAMINER

SLOBODYANSKY, E

ART UNIT

PAPER NUMBER

1652

12

DATE MAILED:

05/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/261,329

Applicant(s)
Andersen et al.

Examiner
Elizabeth Slobodyansky

Group Art Unit
1652



☒ Responsive to communication(s) filed on Mar 6, 2001

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 37-78 is/are pending in the application.

Of the above, claim(s) 38-41 and 44-73 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 37, 42, 43, and 74-78 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

The amendment filed March 6, 2001 (Paper No. 11) canceling claims 1-36 and adding claims 37-78 has been entered.

Claims 37-78 are pending.

Rejections and/or objections not reiterated from previous Office action are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

Election/Restriction

Applicant's election with traverse of Group III in Paper No. 11 is acknowledged. The traversal is on the ground(s) that Groups I-XII are classified in class 435, subclass 209 and that some mutations are overlapping and that examination of Groups I-XII is not a burden on the examiner. This is not found persuasive because class 435, subclass 209 comprises thousands of patents given to distinct inventions. In the instant case, inventions I-XII are patentably distinct as directed to different variants of different enzymes. Taken into account the number of mutations, thorough examination of the groups together would represent a serious burden on the examiner.

The requirement is still deemed proper and is therefore made FINAL.

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Newly submitted claims 38-41 and 44-73 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: they are drawn to variants not included in the scope of claims 11-19. Claims 37 and 74-78 will be examined to extent they include mutations present in claims 11-19.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 38-41 and 44-73 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

Claims 74-76 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 74 recites SEQ ID NO:1 to which independent claim 37 is limited.

Claims 75 and 76 encompass mutations not included in claim 37 from which they depend.

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Claim Rejections - 35 USC § 112

Claim 37, with dependent claims 42, 43 and 74-78, is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 37 is directed to a genus of a modified cellulase of SEQ ID NO:1 comprising specific mutations. Because "comprising " is open language the claim does not impose any structural limitations and reads on any structure that is not necessarily homologous with SEQ ID NO: 1.

These claims are directed to a genus of molecules exhibiting endoglucanase activity from any source. The specification teaches the structure of only a single representative species of such endoglucanases, the endoglucanase from *Humicola insolens* DSM 1800 (EGV) having the sequence of SEQ ID NO:1. Therefore, many functionally and structurally unrelated proteins are encompassed within the scope of these claims, including partial amino acid sequences. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality. This is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus.

Given this lack of description of representative species encompassed by the genus of

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the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claim 37, with dependent claims 42, 43 and 74-78, is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a modified endoglucanase having the structure of SEQ ID NO: 1 consisting of specific mutations, does not reasonably provide enablement for any modified endoglucanase having the structure of SEQ ID NO: 1 comprising specific mutations. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Factors to be in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

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Claim 37 is directed to a genus of a modified cellulase of SEQ ID NO:1 comprising specific mutations. Because "comprising " is open language the claim does not impose any structural limitations and reads on any structure that is not necessarily homologous with SEQ ID NO: 1. Therefore, the breadth of these claims is much larger than the scope enabled by the specification.

The state of the art does not allow the predictability of the properties based on the structure. Therefore, one skilled in the art would require guidance beyond that provided in the specification as to how to make a modified endoglucanase from a parent enzyme of unknown structure. Without such guidance, the experimentation left to those skilled in the art is undue.

Claim 37, with dependent claims 42, 43 and 74-78, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 37, 76 and 77 recite positions in SEQ ID NO:1 defined by a figure and a letter such as 42a, for example. However, SEQ ID NO: 1 does not have positions defined in this way.

Claims 75-77 recite positions in SEQ ID NO:1 defined by an asterisk. It is unclear what it means.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

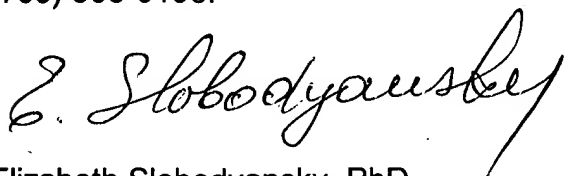
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, reading "E. Slobodyansky". The signature is written in black ink and is positioned above the printed name and title.

Elizabeth Slobodyansky, PhD
Primary Examiner

May 18, 2001